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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,880	09/28/2000	George B. Stefano	09598/004001	6475

7590

06/18/2002

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 06/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/530,880

Applicant(s)

STEFANO ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Formal Matters

- A. Amendment C, filed 3/28/02, has been entered into the record.
- B. Claims 33-40 are pending in this application and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

- A. The objection to the specification has been withdrawn since Applicants have amended the title to one which is indicative of the invention to which the claims are directed.
- B. The objection to the specification has been withdrawn since Applicants have provided an Abstract of the disclosure.

3. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. Claims 33-40 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action dated 12/4/01. Applicants argue that the specification does disclose working examples teaching how to determine the specificity of an estrogen surface receptor (ESR) response. Applicants argue that Example 6 disclose that estrogen surface receptors are specifically inhibited by tamoxifen and not by ICI 182,780. Therefore, a person of ordinary skill in the art would have been capable of determining the presence of an estrogen surface receptor-mediated response without undue experimentation. Applicants also argue that the claims should not be limited to screening agonists for human ESRs since the methods described in the specification can be performed with tissue other than human.

Applicants arguments have been considered and, while the Examiner agrees with Applicants that the claims should not be limited to human tissue, Applicants have still not enabled the claimed methods for identifying an estrogen surface receptor. Applicants have disclosed in Example 6 of the specification that ESR responses are specifically inhibited by tamoxifen and not by ICI 182,780. However, the claims do not recite this limitation. The claims only recite that the ESR response is inhibited by tamoxifen and recite nothing about ICI 182,780. The limitation in the claims that the ESR response is only inhibited by tamoxifen does not enable the artisan to differentiate between an agonist acting at either an ESR, or a

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nuclear estrogen receptor since the actions of both of these receptors are inhibited by tamoxifen. Furthermore, Example 6 of the specification uses an agonist which is known to not cross the cell membrane (E₂-BSA). Therefore, in this case, it is possible for the method in this Example to demonstrate that tamoxifen alone can identify a cell surface. However, the claims do not limit the agonist to one which is not permeable to cell membranes. For this reason as well, the claimed method which only uses tamoxifen to identify an ESR are not enabled. Applicants should amend the claims to recite that the effect of the agonist is inhibited by tamoxifen and not by ICI 182,780.

4. Claim Rejections - 35 USC § 112, second paragraph

A. Claims 33-40 remain rejected under 35 USC 112, second paragraph, for the reasons already of record on pages 4-5 of the Office Action dated 12/4/01. Applicants argue that one of ordinary skill in the art would have understood that no essential steps have been omitted from the claims and that performing these steps would allow the artisan to identify an ESR. However, for the reasons stated in the above rejection under 35 USC 112, first paragraph, claim 33 omits the essential step of either (1) screening for agonists which are known not to cross the cell membrane, or (2) that the activity of the potential estrogen receptor agonist is inhibited by tamoxifen, but not by ICI 182,780. The rejection of these claims regarding the "monitoring of nitric oxide synthase activity" has been withdrawn in view of Applicants' amendments to the claims and in view of their arguments that one of ordinary skill in the art would be able to measure nitric oxide activity.

B. The rejection of claims 33-40 under 35 USC 112, second paragraph, on page 5 of the Office Action dated 12/4/01, has been withdrawn in view of Applicants' arguments that the claims recite methods for identifying that an agonist binds an ESRs, as opposed to a nuclear estrogen receptor, and that there is no need to determine to which ESR the test compound is binding.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.

Patent Examiner

Group 1600

June 17, 2002

Gary L. Kunz
GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
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